APR 0 7 2004 SHEET 1 OF TRADEMAR FORM PTO-1449 ATTY DOCKET NO: CLASSEN=1D SERIAL NO: 09/660,584 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF DOCUMENTS CITED BY APPLICANT APPLICANT: CLASSEN, John Barthelow FILING DATE: September 12, 2000 **GROUP: 1648** U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date) RXAMINER SUB-FILING DATE DOCUMENT NUMBER INITIAL DATE PATENTEE CLASS CLASS IF APPROP. 0 P1 16JUL2002 CLASSEN ₽2 5 7 8 3 R 5 17MAR1998 CLASSEN **P3** 7 2 3 8 3 03MAR1998 CLASSEN FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country) DOCUMENT NUMBER DATE COUNTRY CLASS TRANSLATION CLASS YES/NO OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication) Institute of Medicine, "The Anthrax Vaccine: Is it safe? Does it work?", pp. 1, 3, 136-139, 160-164, 166-170, 246-8, (March 2002). YANG, et al., "Childhood Diabetes in China: Enormous variation by place and ethnic group", KC DIABETES CARE, vol. 21, no. 4, pgs. 525-9, April 1998. KD SANJEEVI, et al., *BCG Vaccination and GAD65 and IA-2 Autoantibodies in Autoimmune Diabetes in ANN. NY. ACAD. SCI., vol. 958:, pgs. 293-296, 2002. CLASSEN, et al., "The Safety of Military Immunization and the Risk of Insulin-Dependent Diabetes", CLINICAL PRACTICE OF ALTERNATIVE MEDICINE, vol. 2, no. 4, pgs. 247-252, 2001 KARVONEN, et al., "Incidence of Childhood Type 1 Diabetes Worldwide", <u>DIABETES CARE</u>, vol. 23, no. 10, pgs. 1516-1526, October 2000. KF DESTEFANO, et al., "Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes Mellitus", PEDIATRICS, vol. 108, no. 6, pgs. 1-5, December 2001. KG CLASSEN and CLASSEN, "Vaccines and the risk of insulin-dependent diabetes (IDDM): potential mechanism of action", MEDICAL HYPOTHESES, vol. 57(5), pgs. 532-538, 2001. ΚI CLASSEN and CLASSEN, "Clustering of Cases of Insulin Dependent Diabetes (IDDM) Occurring Three Years After Hemophilus Influenza B (HiB) Immunization Support Causal Relationship Between Immunization and IDDM*, <u>AUTOIMMUNITY</u>, vol. 35, pgs. 247-253, 2002. WAHLBERG, et al., "Vaccinations May Induce Diabetes-Related Autoantibodies in One-Year-Old Children", ANN. N.Y. ACAD. SCI., vol. 1005, pgs. 404-408, 2003. KJ DESTEFANO, et al., "Childhood vaccinations and risk of asthma", PEDIATR. INFECT. DIS. J., vol. KK 21, no. 6, pgs. 498-504, 2002. RIMINTON, et al., *Dermal Enhancement: Bacterial Products on Intact Skin Induce and Augment Organ-Specific Autoimmune Disease", THE JOURNAL OF IMMUNOLOGY, vol. 172, pgs. 302-309, 2004 KM *Immunization with BCG vaccine starting after age 1 is associated with increased risk of IDDM in Quebec", (unpublished reanalysis of Parent (1997)). CLASSEN, "Vaccines modulate IDDM", DIABETOLOGIA, 39:500-501 (1996). KN KO M-M-R II, vaccine Physicians Package Insert pp. 7 & 9 (1999). KP CLASSEN, et al, "Clustering of Cases of Type 1 Diabetes Mellitus Occurring 2-4 Years After Vaccination is Consistent with Clustering After Infections and Progression of Type 1 Diabetes Mellitus in Autoantibody Positive Individuals", JOURNAL OF PEDIATRIC ENDOCRINOLOGY & METABOLISM

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\dagger		Pediatric Infectious Disease								
7									`.	1999
V		Boumpas et al., Annals of I								07/1995
w		Benveniste, pp. 346-364, a & Sons, New York.	and Lagrange et a	l., pp. 46!	5-502, in Immunolog	y, Bach et al	., ed., Jo	ohn Wil	еу	1982
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U. S. Patent and Tredemark Office PTO-892 (Rev. 9-95)

Notice of References Cited

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Notice of References Cited

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	A	5,139,776		Chazano	et al.	-		
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NON-PATENT DOCUMENTS

		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
A	U	Adorini et al. Trends in Immunololgy 18(5): 209-211	1997
	v	Miller et al. The Biological and Clinical Basis of Infectious Diseases, Chapter 3, pages 15-28	1997
	w	John Brit. Med. Journal. 289:881-882	1984
0	×	Halsey et al. Bulletin of the World Health Organization 63(6): 1151-1169	1985

U. S. Patent and Trademark Office PTO-892 (Rev. 9-95)

Notice of References Cited

Part of Paper No. 7



Notice of References Cited

Application No. Applicant(s) 08/591,651

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	لم	Dengrove et al. Pediatric	Research 20(8)	: 725-739				
1	\mathcal{F}							1986
4	1	Madore et al. Pediatrics 8	35(3): 331-337	•	•	•		
	V							1990
	w	Hayes, Science 260: 127	79-1286					1993
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(Zuckerman et al. J. Hepa	tol. 22(Suppl. 1): 97-100				1005
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U. S. Patent and Trademark Office PTO-892 (Rev. 9-95)

Notice of References Cited

Part of Paper No. ___7

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Notice of References Cited

Application No. Applicant(s) Class

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7 1 R		FILING DATE: February 12, 1996	
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	VAUTIER, et al., <u>Acute Sero-Positive Rh</u> HEUMATOLOGY, vol. 33, pg. 991, 199	neumatoid Arthritis Occurring after Hepatitis Vacci 94.	nation, BRITISH JOURNAL OF
2 J	KELTON, et al., <u>Vaccination-Associated</u> anuary 23/30, 1981.	Relapse of Immune Thrombocytopenia, JAMA, vo	ol. 245, no. 4, pgs. 369-371,
3	FLETCHER, et al., <u>Rare Disease</u> , CLINIC	AL EPIDEMIOLOGY- the essentials, chapter 10, p	gs. 168-173, 1982.
4 P	AHO, et al., <u>Transient Appearance of the PATHOL</u> . MICROBIAL SCAN., vol. 46, p	ne Rheumatoid Factor in Connection with Prophyla ng. 478-479, 1962.	actic Vaccinations, ACTA
5 <u>F</u>	SCHATTNER, et al., Poliovaccines and Patients, VACCINE, vol. 10, Issue 2, pg	the Course of Systemic Lupus Erythematosus- a F s. 98-100, 1992.	Retrospective Study of 73
6	BRITTON, et al., <u>Possible Interactions E</u> NEUROL., vol. 35, pg. 693, October 19	Between Rabies Vaccination and a Progressive Dec 78.	generative CNS Disease, ARCH
	TORO, et al., Neuroparalytic Accidents vol. 34, pgs. 700, November 1977.	of Antirables Vaccination with Suckling Mouse Br	rain Vaccine, ARCH NEUROL.,
8 (LOUIE, et al., <u>Clinical and Antibody Res</u> OF INTERNAL MEDICINE, vol. 88, no. 6	sponses After Influenza Immunization in Systemic 6, pgs. 790-792, June 1978.	Lupus Erythematosus, ANNALS
9 1	RISTOW, et al., <u>Influenza Vaccination c</u> MEDICINE, vol. 88, pgs. 786-789, 197	of Patients with Systemic Lupus Erythematosus. A 8.	ANNALS OF INTERNAL
10	WILLIAMS, et al., <u>Influenze Immunizati</u> no. 6, pgs. 729-734, June 1978.	on in Systemic Lupus Erythematosus, ANNALS O	F INTERNAL MEDICINE, vol. 88
11	PEELER, et al., Intensive Immunization	of Man, ANNALS OF INTERNAL MEDICINE, vol. 6	53, no. 1, pgs. 44-57, July 196
12	WHITE, et al., <u>Repeated Immunization:</u> 600, 1974.	Possible Adverse Effects, ANNALS OF INTERNAL	L MEDICINE, vol. 81, pgs. 594-
13	SINANIOTIS, et al., <u>Diabetes Mellitus A</u> pg. 749, 1975.	After Mumps Vaccination, ARCHIVES OF DISEASI	ES OF CHILDHOOD, vol. 50(9),
14	SULTZ, et al., <u>Is Mumps Virus an Etiol</u> no. 4, pgs. 654-656, April 1975.	logic Factor in Juvenile Diabetes Mellitus?, THE JO	OURNAL OF PEDIATRICS, vol. 8
15	CHAMPSAUR, et al., <u>Virologic, Immur</u> OF PEDIATRICS, vol. 100, no. 1, pgs.	nologic, and Genetic Factors in Insulin-Dependent 15-20, January 1982.	Diabetes Mellitus, THE JOURNA
EXAMINER		DATE CONSIDERED 2//	8/0(

		ATTY DOCKET NO:	SERIAL NO:
FORM PTO-144	9 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO: CLASSEN = 1A	08/591,651
LIST DO	CUMENTS CITED BY APPLICANT	APPLICANT:	
	several sheets if necessary)	CLASSEN, John B.	
		FILING DATE: February 12, 1996	GROUP: 1813
	OTHER DOCUMENTS (include author, ti	itle, name of publication, volume, pages	and date of publication)
16	FESCHAREK, et al., Measles-Mumps Va and Analysis of Spontaneously Reported	accination in the FRG: an Empirical Analy I Side Effects, VACCINE, vol. 8, pgs. 44	rsis After 14 Years of Use. II. Tolerabilit 6-456, October 1990.
.17	HELMKE, et al., Islet Cell Antibodies an Mumps Vaccination, DIABETOLOGIA, vo	d the Development of Diabetes Mellitus ol. 29, pgs. 30-33, 1986.	in Relation to Mumps Infection and
18	VAANDRAGER, et al., <u>Islet Cell Antibou</u> 1986.	dies, Mumps Infection and Mumps Vacci	nation, DIABETOLOGIA, vol. 29, pg. 40
19	BODANSKY, et al., <u>Does Exposure to F</u> pgs. 611-614, 1990.	Rubella Virus Generate Endocrine Autoim	munity?, DIABETIC MEDICINE, vol. 7,
20	BLOM, et al., The Swedish Childhood [Diabetes Study, DIABETOLOGIA, vol. 34	, pgs. 176-181, 1991.
21	DAHLQUIST, et al., The Swedish Child Different Age Groups, DIABETOLOGIA,	hood Diabetes Study - a Multivariate An vol. 34, pgs. 757-762, 1991.	alysis of Risk Determinants for Diabetes
. 22	HOOVER, Robert N., Bacillus Calmette Experience, CANCER RESEARCH, vol. 3	-Guerin Vaccination and Cancer Preventi 36, pgs. 652-654, February 1976.	on: A Critical Review of the Human
23	CLEMENS, et al., <u>BCG Prophylaxis Aga</u> DIS., vol. 37, no. 1, pgs. 45-54, 1984.	ainst Cancer: Methodological Evaluation	of a Continuing Controversy, J. CHRON
. 24	GRANGE, et al., <u>BCG Vaccination and</u>	Cancer, TUBERCLE, vol. 71, pgs. 61-64	, 1990.
25	ENGLEMAN, et al., <u>Treatment of NZB/</u> <u>Preparations Accelerates Autoimmune</u>	NZW F, Hybrid Mice with Mycobacteriur Disease, ARTHRITIS AND RHEUMATISM	m Bovis Strain BCG or Type II Interferon 1, vol. 24, no. 11, November 1981.
26	KLEMPARSKAYA, N., <u>Autohaemolysin</u> pgs. 11-15, 1973.	n-Producing Cells in Mice Injected with B	acterial Vaccines, IMMUNOLOGY, vol. :
27	ONICA, et al., <u>Autoantiboides Detecte</u> INFECTION AND IMMUNITY, vol. 18, p	od in Rabbits Hyperimmunized with Group pgs. 624-628, 1977.	o A, C, and G Streptococcal Vaccines,
28	COLLING, et al., Association of Bacter by Group C, Group B Type III, and Stre IMMUNITY, vol. 41, no. 1, pgs. 205-2	rial Carbohydrate-Specific Cold Agglutini eptococcus pneumoniae Type XIV Strept 13, July 1983.	n Antibody Production with Immunization ococcal Vaccines, INFECTION AND
29	· }	sformation of Allergic Encephalomyelitis	by Pertussis Vaccine, PSEBM, vol. 112
29Ь		uated Vaccines on the Course of Experim 7.	nental Allergic Encephalomyelitis, EUR.
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EXAMINER			

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO: CLASSEN = 1A	SERIAL NO: 08/591,651						
								
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	FILING DATE: February 12, 1996	GROUP: 1813						
OTHER DOCUMENTS (include author, ti	tle, name of publication, volume, pages and date of	publication)						
RONNEBERGER, et al., Allergic Encephalomyelitis in Rats - Toxicity Assay for Pertussis Vaccines, ARCH. TOXICOL., Suppl. 4, pgs. 179-183, 1980.								
KALLEN, et al., Effect of Bordetella Pertussis Vaccine on Experimental Autoimmune Encephalomyelitis in Rats, INT. ARCHS ALLERGY APPL. IMMUN., vol. 80, pgs 95-99, 1986.								
TWAROG, et al., The Adjuvant Effect of pgs. 434-439, 1968.	f Pertussis Vaccine in Experimental Thyroiditis of the	a Rat, P.S.E.B.M., vol. 130,						
RUDOFSKY, U.H., Studies on the Pathogenesis of Experimental Autoimmune Renal Tubulointerstitial Disease in Guinea- Pigs, CLIN. J. IMMUNOL., vol. 25, pgs. 455-461, 1976.								
HELMKE, et al., Response from the Aut	hors, DIABETOLOGIA, vol. 29, pgs. 407, 1986.							
ROSENTHAL, et al., <u>Cancer Precursors</u> PHARMACOTHERAPY, vol. 38, pgs. 42	and their Control by Stimulation of the Immune Sys 9-433, 1984.	tem, BIOMEDICINE &						
ROSENTHAL, et al., <u>Cancer Precursors</u> 1986.	and their Control by BCG, DEVELOP, BIOL, STAND	ARD, vol. 58, pgs. 401-416,						
HYOTY, et al., <u>Decline of Mumps Antib</u> Incidence of Type 1 Diabetes After Intro 36, pgs. 1303-1308, 1993.	odies in Type 1 (insulin-dependent) Diabetic Childre Eduction of the Mumps-Measles-Rubella Vaccine in F	n and a Plateau in the Rising iinland, DIABETOLOGIA, vol.						
								
1/6	DATE CONSIDERED \$	18/65						
	RONNEBERGER, et al., Allergic Encepha Suppl. 4, pgs. 179-183, 1980. KALLEN, et al., Effect of Bordetella Pert ARCHS ALLERGY APPL. IMMUN., vol. 8 TWAROG, et al., The Adjuvant Effect of pgs. 434-439, 1968. RUDOFSKY, U.H., Studies on the Pathopigs, CLIN. J. IMMUNOL., vol. 25, pgs. HELMKE, et al., Response from the Aut ROSENTHAL, et al., Cancer Precursors PHARMACOTHERAPY, vol. 38, pgs. 42 ROSENTHAL, et al., Cancer Precursors 1986. HYOTY, et al., Decline of Mumps Antity Incidence of Type 1 Diabetes After Intro 36, pgs. 1303-1308, 1993.	OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of RONNEBERGER, et al., Alleraic Encephalomyelitis in Rats - Toxicity Assay for Pertussis Vac Suppl. 4, pgs. 179-183, 1980. KALLEN, et al., Effect of Bordetelle Pertussis Vaccine on Experimental Autoimmune Enceph ARCHS ALLERGY APPL. IMMUN., vol. 80, pgs 95-99, 1986. TWAROG, et al., The Adjuvant Effect of Pertussis Vaccine in Experimental Thyroiditis of the pgs. 434-439, 1968. RUDOFSKY, U.H., Studies on the Pathogenesis of Experimental Autoimmune Renal Tubulois Pias, CLIN. J. IMMUNOL., vol. 26, pgs. 455-461, 1976. HELMKE, et al., Response from the Authors, DIABETOLOGIA, vol. 29, pgs. 407, 1986. ROSENTHAL, et al., Cancer Precursors and their Control by Stimulation of the Immune Sys PHARMACOTHERAPY, vol. 38, pgs. 429-433, 1984. ROSENTHAL, et al., Cancer Precursors and their Control by BCG, DEVELOP, BIOL. STAND 1986. HYOTY, et al., Decline of Mumps Antibodies in Type 1 (insulin-dependent) Diabetic Childre Incidence of Type 1 Diabetes After Introduction of the Mumps-Measles-Rubella Vaccine in F36, pgs. 1303-1308, 1993.						

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FORM PTO	-1449									S. DEPARTMENT OF COMMERCE TENT AND TRADEMARK OFFICE	ATTY DOCKET CLASSEN=1	NO.		SERIAL 08/104	
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h	AP Baraff et al, "Immunologic Response to Early and Routine DTP Immunization in Infants", <u>Pediatrics</u> , <u>73</u> :37-42 (January 1984)														
	Barrett et al, "Multiple Antigen for Immunization Against Poliomyelitis, Diphtheria, Pertussis, and Tetanus' JAMA, 167:1103-1107 (June 28, 1958)														
Barrett et al, "Multiple Antigen Immunization of Infants Against Poliomyelitis, Diphtheria, Pertussis, and Tetanus", Pediatrics, pp.720-736 (November 1962)															
EXAMINER DATE CONSIDERED 3/18/00															
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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE CLASSEN=1 08/104,529 LIST OF DOCUMENTS CITED BY APPLICANT APPLICANT: CLASSEN, J. Barthelow (Use several sheets if necessary) FILING DATE: August 12, 1993 GROUP OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication) Blom, et al., "The Swedish childhood diabetes study: Vaccinations and Infections as risk determinants for diabetes in childhood", <u>Diabetologia</u>, <u>34</u>:176-181 (1991) AS Classen, et al., Evidence That Cyclosporine Treatment During Pregnancy Predisposes Offspring to Develop Autoantibodies, Transplantation, Vol 51, No. 5, pp. 1052-1057, May 1991 AT Dengrove et al, IgG and IgG Subclass Specific Antibody Responses to Diphtheria and Tetanus Toxoids in Newborns and Infants Given DTP Immunization, Pediatric Research, Vol. 20 No. 8, pp. 735-739, 1986 AU Elias et al, Vaccination against autoimmune mouse diabetes with a T-cell epitope of the human 65-kDa heat A۷ shock protein, Natl. Acad. Sci. USA, Vol. 88, pp. 3088-3091, April 1991 Elias et al, Induction and therapy of autoimmune diabetes in the non-obese diabetic (NOD/Lt) mouse by a 65-kDa heat shock protein, Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 1576-1580, February 1990 ΑW Fagan McInerney, et al., Prevention of Insulitis and Diabetes Onset by Treatment With Complete Freund's ΑX Adjuvant in NOD Mice, Diabetes, Vol. 40, pp. 715-725, June 1991 General Recommendations on Immunization, JAMA, Vol. 262 No. 1, pp. 22-26, July 7, 1989 (from the CDC) AY General Recommendations on Immunization, JAMA, Vol. 262, No 3, pp. 339-340, July 21, 1989 (from the CDC) Grange et al, BCG vaccination and cancer, Tubercle, Vol. 71, pp. 61-64. ΑZ Green et al, Incidence of childhood-onset insulin dependent diabetes mellitus: the EURODIAB ACE study, The Lancet, Vol. 339, pp. 905-909, April 11, 1992 Halsey et al, The efficacy of DPT and oral poliomyelitis immunization schedules initiated from birth to 12 weeks of age, Bulletin of the World Health Organization, Vol. 63 (6), pp. 1151-1169, 1985 BB Harada, et al., Prevention of overt diabetes and insulitis in NOD mice by a single BCG vaccination, Diabetes ВС Research and Clinical Practice, Vol. 8, pp. 85-89, 1990 Huang et al, Pertussigen Treatment Retards, But Fails To Prevent, The Development of Type I, Insulin-Dependent Diabetes Mellitus (IDDM) In NOD Mice, Autoimmunity, Vol. 9, pp. 311-317, 1991 BD Huang et al, The Effect of Pertussis Vaccine on the Insulin-Dependent Diabetes Induced by Streptozocin.in BE Mice, Pediatric Research, Vol. 18, No. 2, pp. 221-226, 1984 Imamura et al, Intrapericardial OK-432 Instillation for the Management of Malignant Pericardial Effusion, Cancer, Vol. 68 No. 3, pp. 259-263, July 15, 1991 BF John, T. Jacob, Immune response of neonates to oral poliomyelitis vaccine, British Medical Journal, Vol. 289, pp. 881, October 6, 1984 BG Kolb et al, Analysis of 22 Immunomodulatory Substances for Efficacy in Low-Dose Streptozotocin-Induced Diabetes, Diabetes Research, Vol. 6, pp. 21-27, 1987 BH Krolewski et al, Epidemiologic Approach to The Etiology of Type I Diabetes Mellitus and its Complications, The New England Journal of Medicine, Vol. 317 No. 22, pp. 1390-1398, November 26, 1987 **EXAMINER** DATE CONSIDERED

EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE CLASSEN=1 08/104,529 DOCUMENTS CITED BY APPLICANT APPLICANT: CLASSEN, J. Barthelow LIST OF (Use several sheets if necessary) GROUP: FILING DATE: August 12, 1993 OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication) Madore et al, Safety and Immunologic Response to Haemophilus Influenzae Type b Oligosaccharide-CRM Conjugate Vaccine in 1- to 6-Month-Old Infants, Pediatrics, Vol. 85 No. 3, pp. 331-337, March 1990 BK Mukai et al, Combination Therapy of Local Administration of OK-432 and Radiation for Esophageal Cancer, BL Int. J. Radiation Oncology Biol. Phys., Vol. 22 No. 5, pp. 1047-1050, 1992 Ogita et al, OK-432 Therapy for Unresectable Lymphangiomas in Children, Journal of Pediatric Surgery, Vol. 26 No. 3, pp. 263-270, March 1991 BM Oldstone, et al., Viruses as Therapeutic Agents, J. Exp. Med., Vol. 171, pp. 2091-2100, June 1990 BN Oldstone, Michael B.A., Prevention of Type I Diabetes in Nonobese Diabetic Mice by Virus Infection, Science, Vol. 239, pp. 500-502, January 29, 1988 RO Pabst et al, Effect of breast-feeding on antibody response to conjugate vaccine, The Lancet, Vol. 336, RP pp. 269-270, August 4, 1990 Pearce et al, Studies of Concanavalin A in Nonobese Diabetic Mice. 1. Prevention of Insulin-Dependent BQ Diabetes, The Journal of Pharmacology Experimental Therapeutics, Vol. 258 No. 2, pp. 710-715, 1991 Perkins et al, Serological Response of Infants To Poliomyelitis Vaccine, British Medical Journal, pp. 68-71, July 12, 1958 Provenzano et al. Immunization and Antibody Response in the Newborn Infant, The New England Journal of BS Medicine, Vol. 273, No. 18, pp. 959-965, October 28, 1965 Sadelain, et al., Prevention of Type I Diabetes in NOD Mice by Adjuvant Immunotherapy, Diabetes, Vol. 39, BT pp. 583-589, May 1990 Satoh et al, Treatment With Streptococcal Preparation (OK-432) Suppresses Anti-Inlet Autoimmunity and Prevents Diabetes in BB Rats, Diabetes, Vol. 37, pp. 1188-1194, September 1988 BU Satoh et al, Recombinant Human Tumor Necrosis Factor « Suppresses Autoimmune Diabetes in Nonobese Diabetic ΒV Mice, Rapid Publication, Vol. 84, pp. 1345-1348, October 1989 Schwimmbeck, et al., Abrogation of Diabetes in BB Rats by Acute Virus Infection, Association of Viral-Lymphocyte Interactions, The Journal of Immunology, Vol. 140, No. 10, pp. 3394-3400, May 15, 1988 BW Seino et al, Inhibition of autoimmune diabetes in NOD mice with serum form streptococcal preparation BX (OK-432)-injected mice, Clin. exp. Immunol., Vol. 86, pp. 413-418, 1991 Shintani, et al., Mechanism of Action of A Streptococcal Preparation (OK-432) in Prevention of Autoimmune Diabetes in NOD Mice, The Journal of Immunology, Vol. 144, No. 1, pp. 136-141, January 1, 1990 BY Simultaneous Administration of Multiple Vaccines, Active Immunization, pp. 16-19 BZ Spigland et al, Immunization of Infants With Formalinized Poliomyelitis Vaccine (Salk Type), Pediatrics, Vol. 25, pp. 812-821, May 1960 CA **EXAMINER** DATE CONSIDERED

EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-	1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CLASSEN=1	SERIAL NO. 08/104,529							
LIST	0 F	DOCUMENTS CITED BY APPLICANT	APPLICANT: CLASSEN, J. Barthelow								
		(Use several sheets if necessary)	FILING DATE: August 12, 1993	GROUP:							
	01	HER DOCUMENTS (include author, title, name of publication, v	olume, pages and date of publica	tion)							
m	СВ	Toyota et al, Islet Activating Protein (IAP) Derived from the Culture Supernatant Fluid of Bordetella Pertussis: Effect on Spontaneous Diabetic Rats, Diabetologia, Vol. 14, pp. 319-323									
	сс	Toyota et al, Streptococcal Preparation (OK-432) Inhibits Development of Type 1 Diabetes in NOD Mice, Diabetes, Vol. 35, pp. 496-499, April 1986									
	.CD	Vagede et al., Vaccine Technology, Vol. 23, pp. 628-643									
	CE	Wheeley et al, Hepatitis B Vaccine in the Prevention of Perinatally Transmitted Hepatitis B Virus Infection: Final Report on a West Midlands Pilot Study, Journal of Medical Virology, Vol. 30, pp. 113-116, 1990									
	CF	Herold, Kevan C et al, Prevention of Autoimm. Diab. 2/ Nonactivity Anti-CD3 Monoclonal Antibody , Diabetes, Vol. 41, pp. 385-391 Infectious Disease Ch. 3 Prevention of Infection pp. 21-24 "Immunization Procedures for Adults, March 1992									
	cG	Mihara, Masahiko et al, Autoimmune Kidney Disease in MRL/1Pr Indomethacin, <u>J. Pharmacobio-Dyn.</u> , <u>15</u> : 255-259, 1992	Mihara, Masahiko et al, Autoimmune Kidney Disease in MRL/1Pr Mice Inhibited by OK-132; II. Effect of Indomethacin, <u>J. Pharmacobio-Dyn.</u> , <u>15</u> : 255-259, 1992								
	СН	Mihara, M. et al., Autoimmune Kidney Disease in MRL/Mp-Ipr mice inhibited by OK-432, a streptococcal preparation, <u>Clin. exp. Immunol.</u> 78:102-107, 1989									
	CI	Guberski, D.L. et al., Induction of Type I Diabetes by Kilham's Rat Virus in Diabetes-Resistant BB/Wor Rats, Science, 25:1010-1013, 15 November 1991									
	cı	Luh, Kwen-Tay, et al., Comparison of OK-432 and Mitomycin C Pleurodesis for Malignant Pleural Effusion Caused by Lung Cancer, <u>Cancer</u> , <u>69</u> :674-679, February 1, 1992									
	ск	Hems, Gordon et al., B.C.G. and Leukemia, <u>The Lancet</u> , p. 183, January 23, 1971									
	CL	Salonen, Tuula et al., Risk Indicators in Childhood Malignancies, <u>Int. J. Cancer</u> , <u>15</u> :941-946, 1975									
	СМ	Infectious Disease, Chapter 3, Prevention of Infection, Immunization Procedures for Adults, pp. 21-24									
	CN	Shinoda, M. et al., Treatment of advanced renal cell carcine (streptococcal preparation), <u>Acta Urologica Japonica</u> , 38:12	oma with interferon alpha and OK 99-304, November 1992	· 432							
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